

Notice of Allowability

Application No.

10/630,239

Examiner

Humera N. Sheikh

Applicant(s)

SANGHVI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02 October 2006.
2. ☒ The allowed claim(s) is/are 1-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 07/30/2003 are accepted by the Examiner.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/02/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

HUMERA N. SHEIKH
PRIMARY EXAMINER

TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR §1.114 and the Information Disclosure Statement (IDS), both filed 10/02/06 is acknowledged.

Claims 1-23 are pending in this application. No claims have been amended herein. Claims 1-23 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/06 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/02/06 was filed after the mailing date of the Notice of Allowance on 07/12/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

Claims 1-23 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art does not disclose nor teach the instant sustained-release metformin composition comprising the instant combination of hydrophilic components, cross-linking agents and pharmaceutical diluents provided in their respective Markush groupings, with their respective amounts and/or ranges. The prior art fails to disclose or teach a combination of the claimed hydrophilic components, cross-linking agents and pharmaceutical diluents to achieve therapeutically effective blood levels of metformin for up to a 24-hour period. The prior art is lacking in terms of disclosing or teaching the specified incorporation of ingredients in their specific amounts and/or ranges to result in a sustained-release metformin pharmaceutical composition.

The instant invention demonstrates an improvement over prior art formulations in that it provides for therapeutically-effective sustained-release metformin compositions for treating diabetes and related disorders, whereby the metformin provides for improved glucose tolerance in impaired glucose tolerant subjects.

In a telephonic interview held on 07/05/06 between Applicant's representative and the Examiner, suggestions were made to incorporate the specific Markush grouping of pharmaceutical diluents in each of independent claims 1, 13 and 21, as well as incorporating the specific Markush grouping the hydrophilic compound and cross-linking agent in independent claim 21. Suggestions were also made to recite the definition of sustained-release as disclosed in

instant specification, page 12. Applicant's representative agreed to the changes proposed by the Examiner.

Additionally, the IDS filed 10/02/06 has been thoroughly reviewed by the Examiner and was not deemed pertinent over the instant claims, since the disclosure references do not teach the instant active ingredient, a biguanide, metformin (or salts thereof) in combination with the hydrophilic components, cross-linking agents and pharmaceutical diluents claimed, in their respective amounts and/or ranges to yield a sustained-release metformin composition.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

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December 23, 2006


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